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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,781	03/24/2004	Armin Hofmeister	DEAV2003/0025 US NP	4273

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EXAMINER

DAVIS, ZINNA NORTINGTON

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/807,781

Applicant(s)

HOFMEISTER ET AL.

Examiner

Zinna Northington Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/14/06 & 8/24/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) contin.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

3) IDS filed March 24, 2004 and August 16, 2004

DETAILED ACTION

1. Claims 1-15 are pending.
2. This action is in response to the Communication filed June 14, 2006 and August 24, 2006.
3. As Applicants have pointed out in the Communication of August 24, 2006, duplicative restriction requirements were mailed.
4. The error is regretted.
5. Based upon the Applicants' response, the elected invention is Group I, claims 1-7, 14, and 15. At page 43, the elected species is Example 2.

Response to the Applicants' Remarks about the

Restriction Requirement

Applicants state the restriction is improper based upon the following grounds

1. There is no undue burden on the Examiner to search for all of the claims, as they are believed to be in same or similar classifications.
2. Product, process of making them and their uses should be rejoined pursuant to MPEP 821.04.

Applicants submit that the search of all of the claims 1 to 15 should not impose any undue burden on the Examiner. Applicants draw Examiner's attention to the Table shown above, which lists all groupings of the invention. Applicants submit all inventions be rejoined and examined together.

It is the Examiner's position:

- The search will be extended beyond the elected species.

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- While the claims may appear to belong in the same classification, the classification changes based upon the radicals, which are, attached the isoquinoline ring. For instance, if R7, R8, or R9 represent -O_v-SO_w-R47, R47 represents NR48 and R49, which together form a 5, 6, 7, or 8- membered ring. The classification of 546 for the isoquinoline ring no longer controls. There are many instances for this situation. See the instant claims.
- There is an undue burden on the Examiner to search for all the instant compounds and claims.
- **If the elected invention is directed to an allowable product**, pursuant to the procedures set forth in MPEP § 821.04(B), the claims, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, may be rejoined and fully examined for patentability under 37 CFR 1.104.
- The rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.
- Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.
- Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.
- Claims 8-13 are withdrawn from consideration.
- Claims not drawn to the examined subject matter are withdrawn from consideration.

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➤ The requirement is still deemed proper and is therefore made FINAL.

6. Claims 1 –7, 14, and 15 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention for the reasons outlined above. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

7. Claims 1-7, 14, and 15 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are R¹, R², R³, R⁴, R⁵, R⁶, R⁷, R⁸, and R⁹.

8. The examined subject matter is as follows:

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A compound according to formula I wherein at least one of R^7 , R^8 , and R^9 represent $-L-$ G; L represent $-N-C(O)-$; and G represents C_a- . The radicals not defined are as recited in claim 1. Amending the claims to the examined subject matter would overcome the improper Markush objection.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3-6, 7, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 3-6 improperly depend upon claims 1 and 2. See the recitation of the phrase "trifluoroacetates salt".

B. Claim 7 is an essential duplicate of claims 14 and 15.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-7, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck et al. (Reference B1, cited by Applicants).

The instantly claimed compounds are taught. At pages 3-5, see the compounds of the formula. At Table A, page 14, see the preferred embodiments. At Table C, page 19, see the various compounds. The difference between the prior art compounds and the instantly compounds is the selection of the various radicals which are substituted.

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The Beck et al reference teaches the equivalence of H and -NHC(O)- which are substituted at the phenyl ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify any one the compounds of Table C of Beck et al. One of ordinary skill in the art would have been motivated to do this to obtain another of the pharmaceutical compounds preferred by Beck et al., especially since Beck et al clearly suggested that such substitutions would produce a compound with similar properties.

Based upon the teachings of Beck et al, one of ordinary skill in the art of general chemistry would expect that modifying one radical for another would not change the properties of a compound in a significant way. As such, the instantly claimed compounds are unpatentable therefrom.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-7, 14, and 15 are rejected on the ground of nonstatutory double patenting over claims of U. S. Patent No. 6,703,405 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claimed subject matter overlaps. See the definition of the radicals, R7, R8, and R9, attached to the phenyl ring.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.


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15. The Information Disclosure Statements filed March 24, 2004 and August 16, 2004 have been considered.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

17. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Zinna Northington Davis
Primary Examiner
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